

**REMARKS*****Status of the claims***

Claims 2-19 and 54-57 were pending in the present application. By virtue of this response, claims 18, 19, 54 and 55 have been cancelled, claims 2, 12, and 56 have been amended, and new claim 58 has been added. Accordingly, claims 2-17 and 56-58 are currently under consideration. Allowance of the pending claims is respectfully requested.

With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

***Claim Amendments***

Claim 2 has been amended to state that the claimed method comprises identifying and displaying differences or similarities in a *plurality* of lipid metabolites between the plurality of quantitative lipid metabolite profiles. Support for this amendment is found throughout the application as filed (see, e.g., lines 10-16 of page 3, lines 2-13 of page 9, Figure 5, and Figure 7).

Claim 2 has further been amended to indicate that the differences or similarities in the plurality of lipid metabolites between the quantitative lipid metabolite profiles are displayed on a heat map, rather than on a heat map *or* targeting chart.

Additional, minor amendments to claim 2 have also been made to more clearly state the claimed invention.

Claims 18, 19, 54 and 55 have been cancelled and claims 12 and 56 amended due to the above amendments of claim 2.

New claim 58 finds support, e.g., in line 31 of page 12 to line 17 of page 13.

No new matter is added by the above amendments.

***Supplemental Information Disclosure Statement filed March 28, 2006***

Per the Examiner, the Supplemental Information Disclosure Statement filed on March 28, 2006, does not contain legible copies of each reference listed on the list of references (more specifically, Reference Nos. 4 and 8).

In response, enclosed please find copies of the illegible references (Reference Nos. 4 and 8). Please consider these references under 37 CFR 1.97(f) and provide us with an initialed Form SB08 indicating these references have been considered.

***Claim Rejections under 35 U.S.C. § 102***

**Rejection #1 under 35 U.S.C. § 102:**

Claims 2, 3, 12, 55, and 56 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ruan et al. (Journal of Dairy Science, Vol. 81, 1998, pages 9-15) in light of the definition of “Heat map” in Wikipedia (accessed at [http://en.wikipedia.org/wiki/Heat\\_map](http://en.wikipedia.org/wiki/Heat_map) on 6 December 2006). The Examiner alleges that Figure 5 of Ruan et al. is a “heat map because it is a two-dimensional map of multiple lipid profiles marked by shades of colors” (page 7 of the Office Action). Applicants respectfully traverse this rejection.

Claim 2, as amended, is directed to a method for presenting analysis of a plurality of quantitative lipid metabolite profiles, comprising: designating the plurality of quantitative lipid metabolite profiles; identifying differences or similarities in a plurality of lipid metabolites between the quantitative lipid metabolite profiles; and displaying the identified differences or similarities on a heat map. In dependent claim 3, each quantitative lipid metabolite profile comprises quantitative measurements of at least two lipids, and the quantified measurements are obtained using an internal standard for at least one of the lipids. In dependent claim 12, as amended, at least one of the quantitative lipid metabolite profiles is generated using a method comprising: separating a

biological sample into fractions based on a plurality of lipid classes, wherein at least one quantitative internal standard is included for each lipid class; and measuring the quantity of a plurality of lipid metabolites in the fractions. Dependent claim 55 has been cancelled, so the rejection is moot with respect to that claim. In dependent claim 56, an increase or decrease in the lipid metabolite is indicated on the heat map by a color and the relevant amount of the increase or decrease is indicated by the intensity of the color.

Applicants respectfully disagree with the Examiner's characterization of the term "heat map" as meaning "a graphical representation of data where the values taken by a variable in a two-dimensional map are represented as colours" (page 7 of the Office Action). For instance, although the term "heat map" as used in Applicants' specification and claims includes heat maps in which color is used (see, e.g., line 25 of page 37 to line 4 of page 38), the term also includes heat maps in which alternative systems, such as fill patterns, are used to illustrate that there is a change in the level of a metabolite (see, e.g., lines 5-18 of page 38). Additional information regarding the nature of the heat maps referred to in the claims can be found, e.g, from line 4 of page 37 to line 12 of page 39 of Applicants' specification.

To anticipate a claim, a prior art reference must teach or suggest each and every limitation of the claim. Applicants respectfully submit that the Ruan et al. reference does not anticipate claims 2, 3, 12, and 56, because the reference fails to disclose or suggest all elements of claims 2, 3, 12, and 56.

For instance, the Ruan et al. reference does not teach the display of a *single* difference or similarity in a lipid metabolite between a plurality of quantitative lipid metabolites in a heat map, let alone teaches the display of the differences or similarities in a *plurality* of lipid metabolites between the quantitative lipid metabolite profiles in a heat map. Even *if* Crisco vegetable oil were to qualify as a lipid metabolite and Figures 5A and 5B in Ruan et al. were to each represent a lipid metabolic profile, as the Examiner seems to suggest (pages 6-7 of the Office Action), Ruan et al. would still fail to teach or suggest the display of the differences or similarities of the oil in Figure 5A compared to the oil (as reflected in the absence of water) in Figure 5B in a heat map. The difference or similarity between oil levels in Figure 5A and the oil levels in Figure 5B (as indicated by the

absence of water) are not identified and displayed in a heat map in the Ruan et al. reference. For instance, neither Figure 5A nor Figure 5B displays the increase, decrease, or similarity in the quantitative amounts of Crisco vegetable oil in Figure 5A versus Figure 5B. In other words, the Ruan et al. reference does not compare the data in Figure 5A to the data in Figure 5B to identify and display the differences or similarities between the two sets of quantitative data in the form of a heat map. Instead, the two data sets are merely presented side-by-side in Figure 5A and Figure 5B in Ruan et al., and it is left to the reader to attempt to quantitate and/or visualize the similarities and differences between the two data sets, with the intensity of the signal in Figure 5A indicating the level of oil and the intensity of the signal in Figure 5B indicating the opposite (the level of water). Furthermore, since the Ruan et al. reference teaches that the samples in Figure 5A versus Figure 5B are the same and contain known amounts of vegetable oil, the reference teaches no reason to make such a comparison between Figure 5A and 5B.

Furthermore, although Applicants contend that the previously presented and/or original claims 2, 3, 12, and 56 are not anticipated by Ruan et al., claim 2 has nonetheless been amended to reflect the fact that lipid metabolic profiles will typically comprise data relating to more than one lipid metabolite. The Ruan et al. reference further fails to teach or suggest all elements of claim 2, as amended. Even *if* Crisco vegetable oil were to qualify as a first lipid metabolite, the Ruan et al. reference would still fail to teach or suggest a method involving the identification of similarities or differences in a *plurality* of lipid metabolites.

Since the Ruan et al. reference (even in light of the definition of “heat map” in Wikipedia) does not teach or suggest each and every element of claims 2, 3, 12, and 56, as amended, Applicants respectfully request that the rejection of claims 2, 3, 12, and 56 under 35 USC § 102(b) be withdrawn.

Rejection #2 under 35 U.S.C. § 102:

Claims 2, 3, 5, 6, 12, and 54 are rejected under 35 U.S.C. § 102(b) as being anticipated by Wong et al. (Magnetic Resonance in Medicine, 1994, Vol. 32, pages 440-446). In the rejection,

the Examiner asserts that Figure 6 of the Wong et al. reference illustrates a parity plot that is the equivalent of Applicants' "targeting chart."

In the interest of expediting prosecution of the application and without acquiescing as to the merits of the rejection, claim 2 has now been amended to remove the reference to a targeting chart and claim 54 has been cancelled. As indicated above, claim 2, as amended, is directed to a method for presenting analysis of a plurality of quantitative lipid metabolite profiles, comprising: designating the plurality of quantitative lipid metabolite profiles; identifying differences or similarities in a plurality of lipid metabolites between the quantitative lipid metabolite profiles; and displaying the identified differences or similarities on a heat map. Claims 3, 5, 6, and 12 are all dependent claims of claim 2.

As noted above, to anticipate a claim, a prior art reference must teach or suggest each and every limitation of the claim. Applicants respectfully submit that Wong et al. does not anticipate claims 2, 3, 5, 6, and 12, because the reference fails to disclose or suggest all elements of claims 2, 3, 5, 6, and 12. For instance, the Wong et al. reference does not teach or suggest the displaying of differences or similarities in lipid metabolites between a plurality of quantitative lipid metabolite profiles on a *heat map*, and claim 2, as amended, no longer references a targeting chart.

Since the Wong et al. reference does not teach or suggest each and every element of claims 2, 3, 5, 6, and 12, as amended, Applicants respectfully request that the rejection of claims 2, 3, 5, 6, and 12 under 35 USC § 102 be withdrawn.

***Claim Rejections under 35 U.S.C. § 103***

**Rejection #1 under 35 U.S.C. § 103:**

Claims 2 and 57 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wong et al. in view of Moser et al. (Neurochemical Research, Vol. 24, 1999, pages 187-197).

To render a claim obvious, the combination of cited prior art references must teach or suggest each and every claim limitation. Even if the Wong et al. reference is combined with the Moser et al. reference, the combination of references does not teach or suggest each element of claims 2 and 57, as amended. For instance, the references do not teach or suggest the displaying of differences or similarities in a plurality of lipid metabolites between a plurality of quantitative lipid metabolite profiles on a *heat map*.

Since the Wong et al. reference in view of the Moser et al. reference does not teach or suggest each and every element of claims 2 and 57, as amended, Applicants respectfully request that the rejection of claims 2 and 57 under 35 USC § 103 be withdrawn.

Rejection #2 under 35 U.S.C. § 103:

Claims 2, 12, 15, and 16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wong et al. in view of Moser et al. (Neurology) (Moser et al., Annals of Neurology, Vol. 45, 1999, pages 100-110)).

Again, to render a claim obvious, the combination of cited prior art references must teach or suggest each and every claim limitation. Even if the Wong et al. reference is combined with the Moser et al. (Neurology) reference, the combination of references does not teach or suggest each element of claims 2, 12, 15, and 16, as amended. For instance, the references do not teach or suggest the displaying of differences or similarities in a plurality of lipid metabolites between a plurality of quantitative lipid metabolite profiles on a *heat map*.

Since the Wong et al. reference in view of the Moser et al. (Neurology) reference does not teach or suggest each and every element of claims 2, 12, 15, and 16, as amended, Applicants respectfully request that the rejection of claims 2, 12, 15, and 16 under 35 USC § 103 be withdrawn.

Rejection #3 under 35 U.S.C. § 103:

Claims 2, 3, 6, 7, 9, 12, and 13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wong et al. in view of Watkins et al. (Journal of Lipid Research, Vol. 39, 1998, pages 1583-1588).

Even if the Wong et al. reference is combined with the Watkins et al. reference, the combination of references does not teach or suggest each element of claims 2, 3, 6, 7, 9, 12, and 13, as amended. For instance, the references do not teach or suggest the displaying of differences or similarities in a plurality of lipid metabolites between a plurality of quantitative lipid metabolite profiles on a *heat map*.

Since the Wong et al. reference in view of the Watkins et al. reference does not teach or suggest each and every element of claims 2, 3, 6, 7, 9, 12, and 13, as amended, Applicants respectfully request that the rejection of claims 2, 3, 6, 7, 9, 12, and 13 under 35 USC § 103 be withdrawn.

Rejection #4 under 35 U.S.C. § 103:

Claims 2-4, 12, and 14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wong et al. in view of Watkins et al., in further view of Siguel (US Patent 5,075,101; IDS of 1/5/2004) as evidenced by the definition of eicosapentaenoic acid (EPA) ([www.pdrhealth.com](http://www.pdrhealth.com), accessed 6 December 2006).

Even if the Wong et al. reference is combined with both the Watkins et al. and Siguel references, the combination of references still does not teach or suggest each element of claims 2-4, 12, and 14, as amended. For instance, the references do not teach or suggest the displaying of differences or similarities in a plurality of lipid metabolites between a plurality of quantitative lipid metabolite profiles on a *heat map*.

Since the Wong et al. reference in view of the Watkins et al. and Siguel references does not teach or suggest each and every element of claims 2-4, 12, and 14, as amended, Applicants respectfully request that the rejection of claims 2-4, 12, and 14 under 35 USC § 103 be withdrawn.

Rejection #5 under 35 U.S.C. § 103:

Claims 2, 17, and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wong et al. in view of “The World of Membrane Lipids,” [www.biochem.Missouri.edu/~lesa/LIPIDS/membrane\_lipid.html; accessed on 6 December 2006, page made on 2 February 1999].

Claim 19 has been cancelled, thereby rendering the rejection with respect to this claim moot.

Even if the Wong et al. reference is combined with “The World of Membrane Lipids” reference, the combination of references does not teach or suggest each element of claims 2 and 17, as amended. For instance, the references do not teach or suggest the displaying of differences or similarities in a plurality of lipid metabolites between a plurality of quantitative lipid metabolite profiles on a *heat map*.

Since the Wong et al. reference in view of “The World of Membrane Lipids” does not teach or suggest each and every element of claims 2 and 17, as amended, Applicants respectfully request that the rejection of claims 2 and 17 under 35 USC § 103 be withdrawn.

Rejection #6 under 35 U.S.C. § 103:

Claims 2, 17, and 18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ruan et al. in view of “The World of Membrane Lipids,” (www.biochem.Missouri.edu/~lesa/LIPIDS/membrane\_lipid.html; accessed on 6 December 2006, pages made on 2 February 1999) as evidence by the definition of “Heat map” in Wikipedia. Applicants respectfully traverse this rejection.

Claim 18 has been cancelled, thereby rendering the rejection with respect to this claim moot.



As noted above, to render a claim obvious, the combination of cited prior art references must teach or suggest each and every claim limitation. Even if the Ruan et al. reference is combined with “The World of Membrane Lipids” reference, the combination of references still does not teach or suggest each element of claims 2 and 17, as amended. For instance, the references do not teach or suggest the identification of differences or similarities in a plurality of lipid metabolites between quantitative lipid metabolite profiles and does not teach or suggest the display of those differences or similarities on a heat map. (See the discussion above in response to the rejection of claims 2, 3, 12, 55, and 56 under 35 U.S.C. § 102(b) over the Ruan et al. reference. Contrary to the Examiner’s assertions, the Ruan et al. reference does not teach or suggest the identification of differences or similarities in a plurality of lipid metabolites between quantitative lipid metabolite profiles and does not teach or suggest the display of those differences or similarities on a heat map.)

Since the Ruan et al. reference in view of “The World of Membrane Lipids” does not teach or suggest each and every element of claims 2 and 17, as amended, Applicants respectfully request that the rejection of claims 2 and 17 under 35 USC § 103 be withdrawn.

Rejection #7 under 35 U.S.C. § 103:

Claims 2 and 10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wong et al. in view of Grav et al. (Journal of Chromatography B, Vol. 658, 1994, pages 1-10).

Even if the Wong et al. reference is combined with the Grav et al. reference, the combination of references does not teach or suggest each element of claims 2 and 10, as amended. For instance, the references do not teach or suggest the displaying of differences or similarities in a plurality of lipid metabolites between a plurality of quantitative lipid metabolite profiles on a *heat map*.

Since the Wong et al. reference in view of the Grav et al. reference does not teach or suggest each and every element of claims 2 and 10, as amended, Applicants respectfully request that the rejection of claims 2 and 10 under 35 USC § 103 be withdrawn.

Rejection #8 under 35 U.S.C. § 103:

Claims 2, 5, and 8 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wong et al. in view of Dutta et al. (JAOCS, Vol. 74, No. 6, 1997, pages 647-657).

Even if the Wong et al. reference is combined with the Dutta et al. reference, the combination of references does not teach or suggest each element of claims 2, 5, and 8, as amended. For instance, the references do not teach or suggest the displaying of differences or similarities in a plurality of lipid metabolites between a plurality of quantitative lipid metabolite profiles on a *heat map*.

Since the Wong et al. reference in view of the Dutta et al. reference does not teach or suggest each and every element of claims 2, 5, and 8, as amended, Applicants respectfully request that the rejection of claims 2, 5, and 8 under 35 USC § 103 be withdrawn.


**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 475512000100. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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